September 21, 2005

MEMORANDUM

Subject: Technology Review and Residual Risk Data Development for the Ethylene Oxide Commercial Sterilization National Emission Standards for Hazardous Air Pollutants (NESHAP)

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To: Laura McKelvey, Group Leader
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This memorandum summarizes the data development effort that was conducted to support the residual risk and technology reviews of the Ethylene Oxide Commercial Sterilization NESHAP, as required under Section 112(f)(2) and Section 112(d)(6), respectively, of the Clean Air Act (CAA or Act). Section I of this memorandum presents background information on the Ethylene Oxide Commercial Sterilization assessment is presented in a separate memorandum.[a]

I. BACKGROUND

The NESHAP developed under section 112(d) of the CAA for the Ethylene Oxide Commercial Sterilization source category (40 CFR part 63, subpart O) was promulgated on December 06, 1994 (59 FR 62585). The Ethylene Oxide Commercial Sterilization NESHAP covers ethylene oxide, the only hazardous air pollutant (HAP) emitted from the sterilization/fumigation process. The emission points regulated by the Ethylene Oxide Commercial Sterilization NESHAP are the main sterilization and aeration room vents. The majority of sterilization facilities process on a contract basis. Some medical supply manufacturers and spice manufacturers sterilize their own product.

The NESHAP applies to operations at both "major and area sources." A major source is defined in CAA section 112(a)(1) as "any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit

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[a] Memorandum, "Residual Risk Assessment for the Ethylene Oxide Commercial Sterilization Source Category", from Mark Morris, to David Guinnup, Group Leader, Risk & Exposure Assessment Group, OAR, US EPA, February 25, 2005. [Docket OAR-2003-0197]

considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants." An area source has a potential to emit less than a major source. During the development of the NESHAP we estimated that there were approximately 188 facilities nationwide, of which about 47 would be considered major. We estimated that the NESHAP would reduce emissions of ethylene oxide by 1,000 tons annually.

The following is a summary of the NESHAP:

- Main sterilization and aeration room vents subject to control requirements must reduce emissions by 99 percent.

- The standards require an initial performance test, followed by continuous monitoring of specified operating parameters, of vapor processors used to control vent emissions. The monitoring parameter limits are to be established based on data collected during the performance test.

II. STATUTORY AUTHORITY FOR THESE ACTIONS

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of HAP from stationary sources. In the first stage, after EPA has identified categories of sources emitting one or more of the HAP listed in the CAA, section 112(d) calls for us to promulgate national technology-based emission standards for sources within those categories that emit or have the potential to emit any single HAP at a rate of 10 tons or more per year or any combination of HAP at a rate of 25 tons or more per year (known as "major sources"), as well as for certain "area sources" emitting less than those amounts. These technology-based national emission standards must reflect the maximum reductions of HAP achievable (after considering cost, energy requirements, and non-air health and environmental impacts) and are commonly referred to as maximum achievable control technology (MACT) standards.

For area sources, CAA Section 112(d)(5) provides that in lieu of MACT, the Administrator may elect to promulgate standards or requirements which provide for the use of generally available control technologies or management practices and such standards are commonly referred to as generally available control technology (GACT) standards. GACT standards are also technology based standards.

In that final rule, we set MACT for major sources under section 112(d)(2). As for area sources, we established a MACT standard for certain emission points pursuant to section 112(d)(2), and a GACT standard for other emission points pursuant to section 112(d)(5).

Section 112(d)(6)provides that EPA review these technology-based standards and revise

them "as necessary (taking into account developments in practices, processes and control technologies)" no less frequently than every 8 years.

The second stage in standard setting is described in section 112(f) of the CAA. This provision requires, first, that EPA prepare a Report to Congress discussing (among other things) methods of calculating risk posed (or potentially posed) by sources after implementation of the MACT standards, the public health significance of those risks, the means and costs of controlling them, actual health effects to persons in proximity to emitting sources, and recommendations as to legislation regarding such remaining risk. The EPA prepared and submitted this report (``Residual Risk Report to Congress," EPA-453/R-99-001) in March 1999. The Congress did not act on any of the recommendations in the report, triggering the second stage of the standard-setting process, the residual risk phase.

Section 112(f)(2) requires us to determine for each section 112(d) source category whether the national emission standards protect public health with an ample margin of safety. If the national emission standards for HAP "classified as a known, probable, or possible human carcinogen do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in one million," EPA must promulgate residual risk standards for the source category (or subcategory) as necessary to provide an ample margin of safety. The EPA must also adopt more stringent standards to prevent an adverse environmental effect (defined in section 112(a)(7) as "any significant and widespread adverse effect . . . to wildlife, aquatic life, or natural resources . . .."), but must consider cost, energy, safety, and other relevant factors in doing so.

Section 112(f)(5) expressly provides, however, that EPA is not required to conduct any review under section 112(f) or promulgate any emissions limitations under that subsection for any area source listed pursuant to section 112(c)(3) for which EPA has issued GACT standards. Thus, although EPA has discretion to conduct a residual risk review under section 112(f) for area sources for which it has established GACT, it is not required to do so. See CAA section 112(f)(5).

III. DATA DEVELOPMENT FOR PERFORMING THE RESIDUAL RISK REVIEW

Our approach for conducting the data development effort necessary to support the residual risk assessment for the Ethylene Oxide Commercial Sterilization NESHAP included two primary objectives. The first objective was to gather the data necessary to determine the existing residual risk from facilities in the source category that are subject to the control requirements of the NESHAP. The second objective was to determine the potential for achieving further reduction of emissions (and, thus, the risk) from those facilities. Section III-A of this memorandum discuss the development of the data needed to perform the residual risk assessment and Section III-B discusses our evaluation of additional controls available to reduce the risk.

A. DATA GATHERING

To evaluate the residual risk from the Ethylene Oxide Commercial Sterilization source category after implementation of the Ethylene Oxide Commercial Sterilization and Fumigation NESHAP we identified those facilities subject to the control requirements of the standard and described their site locations, operations, and emissions. During the development of the Ethylene Oxide Commercial Sterilization and Fumigation NESHAP, EPA gathered information from a variety of sources to describe and characterize the industry, the amount of HAP emitted, the emission sources, the control measures that were in use or available, and the projected emission reductions and costs of implementing the standards. However, the data were primarily gathered prior to 1987 and significant consolidation in the industry made it necessary to reassess plant emission characteristics. The following paragraphs describe the data gathering activities conducted for this residual risk study. Approximately 100 facilities were ultimately identified to be commercial sterilizers.

Source Identification.[b] The data were gathered primarily from the following three sources: (1) the 1999 National Emissions Inventory (NEI); (2) the 2000 Toxics Release Inventory (TRI); and (3) The Ethylene Oxide Sterilization Association (EOSA) review of the data set. A limited number of facilities were contacted directly to verify the data.

In the U.S. 74 ethylene oxide sterilization facilities were identified from the NEI data base. The 1999 NEI primarily provided location, emission point, control efficiency, and stack characteristic data, though the latter two types of data were available for only about a third of the ethylene oxide facilities identified in the NEI.

The 2000 TRI became available in June 2002. We subsequently extracted facility identification, location, emissions, and control efficiency data for all ethylene oxide emitters (157 facilities), reduced the list to ethylene oxide sterilization facilities by eliminating obvious chemical manufacturers and other non-ethylene oxide facilities, and refined and corrected the data as needed (e.g., for facilities that did not report fugitive emissions). We made several phone calls and conducted internet searches to determine whether some of the larger facilities were still operating and, if so, what their status was in terms of compliance with the MACT.

TRI data from 1999 and earlier data were used for some facilities if 2000 data were not available or we needed to assess changes in emissions over time. TRI data also were useful for determining ethylene oxide use.

The facilities we identified as being subject to the Ethylene Oxide Commercial Sterilization and Fumigation NESHAP cover a range of processes, throughputs, emission levels, product mix, and locations.

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[b] Memorandum, "Data and assumptions used for the screening-level residual analysis of the commercial ethylene oxide sterilizers and fumigators source category", from Alex Koppel, Jim Laurenson, Marsha Fisher and David Burch, ICR to Mark Morris and David Markwordt OAR, US EPA, June 09, 2004. [Docket OAR-2003-0197]

Source Characterization [c] To assess the risk posed by HAP emissions from the ethylene oxide commercial sterilization source category, detailed site specific information is necessary. Modeling inputs such as latitude and longitude of the emission points, HAP emission rates, stack parameters, and distance to fence line are used to perform the actual risk modeling. Other variables such as information on the number and capacities of emission sources, and knowledge of the types and efficiencies of control measures in use are used to help understand the modeling results.

Not all the data fields in the NEI are populated with data; and while the entries for some facilities had details on each emission source, many others had partial data or data for the total facility only. For missing key parameters (such as stack height, stack diameter, and exit gas temperature and velocity) the NEI uses default entries based on industry average values. Latitude and longitude defaults are based on the facility street address and ZIP code.

In some cases, however, we were able to supplement the NEI data base with information obtained from industry contacts or industry representatives. The Ethylene Oxide Sterilization Association (EOSA) submitted detailed data several times over the course of this data gathering. In August 2002, EOSA updated or provided data for all modeling parameters for approximately 20 facilities. In March 2003, EOSA submitted updated data for both the August 2002 facilities and an additional 26 facilities for a total of 46 facilities.

The residual risk modeling identified 44 of 76 facilities with a census block individual lifetime cancer risk at or above 1 in a million, 19 with a census block individual lifetime cancer risk at or above 10 in a million, and 0 with a census block individual lifetime cancer risk at or above 100 in a million.[a]

B. EVALUATION OF ADDITIONAL CONTROLS AVAILABLE TO REDUCE RISK

Facilities in the Ethylene Oxide Commercial Sterilization source category typically emit ethylene oxide from the sterilization chamber and the aeration room. There are 3 emission vents associated with the sterilization and fumigation process: the main sterilization and the chamber exhaust vents from the sterilization chamber and the aeration room vent from the aeration room. As explained below the chamber exhaust vent is not subject to control. The current standard requires MACT control of emissions from the main sterilization vents at both major and area sources. The standards also require MACT control of emissions from aeration room vents from major sources. This section will present the technological feasibility of additional controls to reduce residual risk from this emission source category.

Sterilization chambers are filled with products, sealed, and infused with ethylene oxide to sterilize/fumigate the product. At the conclusion of the sterilization period, the ethylene oxide is pumped from the chamber to a control device. After sufficient removal of ethylene oxide from the chamber, the sterilized product is removed and placed in an aeration room. The purpose of the aeration room is to drive off any ethylene oxide residual left in the product after removal of

ethylene oxide from the sterilization chamber. Ethylene oxide driven off in the aeration room is routed to a control device.

Many, if not all, source facilities utilize a chamber exhaust fan while personnel are removing product from the sterilization chamber. This fan removes ethylene oxide off-gassing from the product. The Ethylene Oxide Commercial Sterilization and Fumigation NESHAP promulgated in 1994 (59 FR 62585) required control of the chamber exhaust vent. In 1997 there were a series of explosions associated with control of the chamber exhaust vent (62 FR 64736). We subsequently reassessed the control requirements and removed the requirement to control the chamber exhaust in November 2001 (66 FR 55577); the Agency continues to believe that the action taken in 2001 is reasonable and we have found no safe way to impose controls on the chamber exhaust vents.[c] Approximately 1 percent of the ethylene oxide used in the process is emitted through the chamber exhaust vent.

The Ethylene Oxide Commercial Sterilization and Fumigation NESHAP requires that a control device must achieve a 99 percent reduction in ethylene oxide emissions for both the main sterilizer vent and aeration room vent subject to emission reduction requirements. Current control technology used to control ethylene oxide emissions includes scrubbers, combusters, dry-bed absorbers, or a combination of these devices. During our investigation of the safety issue associated with the chamber exhaust vent we did not find any new technology for the any of the vents. Some facilities are already using combinations of the current control technologies to achieve the standards. We have no data supporting a further reduction in emissions by adding down-stream control devices to existing control equipment achieving the standards. Major and area source vent characteristics are similar so the same technologies are used for both major and area sources. Therefore, our conclusions concerning new technology apply to the all vents.

Ethylene oxide emissions could be eliminated by using alternatives to ethylene oxide (e.g., chlorine dioxide, gas plasma, hydrogen peroxide, and ozone). However, these chemicals do not necessarily offer environmental improvements over ethylene oxide. None of these alternatives can replace the use of ethylene oxide in all applications. More importantly, ethylene oxide is extremely effective as a sterilant.(see appendix).

The Food and Drug Administration (FDA) has primary authority to regulate the use of sterilization methods. The FDA issued guidance [510(k) Sterility Review Guidance K90-1, August 30, 2002 ("FDA Guidance")] to facilitate non-traditional sterilization methods. The FDA stated in the guidance that the FDA "has had little or no experience with these methods for achieving sterilization and is concerned about a manufacturer's ability to successfully use such methods without adversely affecting the sterility assurance level...". If the use of ethylene oxide

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[c] Press release, Sterigenics, Incident in Sterigenic's Ontario, California Facility, August 20, 2004: "Sterigenics International, Inc. announced today that it had a serious incident involving an explosion within its Ontario, California facility on August 19, 2004." California currently requires control of rear chamber exhaust. [Docket OAR-2003-0197]

were prohibited, manufacturers of products requiring sterilization will have to reconsider the device and packaging material, its compatibility with the nontraditional sterilizing agent, the packaging configuration, the ability of the nontraditional sterilant to penetrate the packaging, the cost, and availability. Because these nontraditional sterilization methods are less known, manufacturers would have to submit to FDA their validation data for review. Nontraditional sterilization operations can not be used to sterilize materials until they have been validated. Prohibiting the use of ethylene oxide carries the risk of creating a void where some products may not be able to be sterilized until newer systems are designed and validated. Until such time as these non-traditional sterilization techniques may be used under FDA rules, these techniques are not considered available for the purpose of reducing emissions.

Radiation (gamma and electron beam) can be used to sterilize many products. Radiation sterilization has been used for about half of the products sterilized in the United States. However, all sterilization techniques are limited in their applications. For example, gamma radiation has potentially damaging effects on products, particularly those products that contain polymers. And, radiation technology is completely different from chamber sterilization. "Ethylene oxide and radiation technologies (both gamma and e-beam) share no common equipment. Any conversion would involve scrapping the ethylene oxide chambers and the related specialized equipment and systems and likely displace most if not all the existing workforce, in effect shuttering the ethylene oxide sterilization industry. Additionally, not even the buildings could be saved. To construct a radiation facility special shielding (huge concrete/lead shields) and storage pools need to be incorporated in to the design of both the building and the process."[d]

EPA did not quantify the costs associated with an ethylene oxide prohibition. We believe the annual costs of a prohibition would likely exceed the annul costs of the original control requirements i.e., approximately $7,000,000 per year.

III. TECHNOLOGY REVIEW

In addition to the requirements in section 112(f)(2) to review the residual risks, section 112 (d)(6) of the CAA requires us to review, and revise as necessary (taking into account developments in practices, processes, and control technologies), emission standards promulgated under this section no less often than every 8 years. The Ethylene Oxide Commercial Sterilization and Fumigation NESHAP was promulgated on December 6, 1994. We subsequently reassessed the MACT requirements and removed the requirement to control the chamber exhaust in November 2001 (66 FR 55577). Our investigation did not identify any significant developments in practices, processes, or control technologies since promulgation of the original standard in 1994.

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[d] Letter from Joseph E. Hadley, Jr., EOSA to David Markwordt, EPA, "Whether EtO facilities could be retrofitted to use radiation technology," October 5, 2004. [Docket OAR-2003-0197]

Existing Sources:

Because we conclude there are no significant developments in practices, processes, or control technologies for both existing major and area sources, the rationale for both controlled and uncontrolled vents in the original MACT and GACT determinations remains unchanged. [59 FR 10591, March 7, 1994 and FR 59 62585 December 6, 1994]

New Major Sources:

While no additional control technologies have been identified that could provide improved control of emissions, we are aware of existing State rules which have control limits exceeding the 99% MACT requirement. The State of California emission reduction requirement for the main sterilizer vent is 99.9% reduction; this requirement was enacted prior to promulgation of the Federal requirements.

We do not have data to confirm that all facilities are capable of achieving 99.9% on a continuous basis. Prior to 1994, we did limited testing; the tests were performed to develop a sampling train necessary for performance testing of ethylene oxide control technology. The results of one of the three tests performed showed the control unit with an emission reduction slightly below 99%. In 1994, it was our understanding California did not have sufficient performance tests to demonstrate continuous compliance with 99.9% for all operating conditions for both scrubbers and combustion units within the industry. Therefore, in 1994, in support of the Federal control limit, we concluded both rules are sufficiently stringent to require application of the same technologies. We believe it reasonable to assume the same technologies perform similarly i.e., those facilities outside of California are on average likely to achieve emission reductions similar to those inside California.

Both the EPA and California rules require a test to demonstrate compliance with the emission reduction limit and continuous monitoring to ensure proper operation and maintenance. We believe these test requirements are sufficient to ensure maximum achievable control technology is in place and operated properly. Initial compliance tests are performed one time and on a very narrow set of operating conditions. These test results are too limited to determine if there are any meaningful differences in control technology lifetime performance associated with a 99% and 99.9% performance limit.

In the absence of data supporting a higher control limit for new major sources, the control requirements for new major facilities will remain unchanged.

New Area Sources:

In the original area source determination, MACT for new area sources was rejected because of the high incremental cost effectiveness. The Administrator employed his authority

under section 112(f) of the Clean Air Act to base the standards for new area sources on GACT. We have no reason to believe the capital cost developed in the original determination have decreased. Therefore, the rationale for GACT for new area sources remains unchanged. [59 FR 10591, March 7, 1994 and FR 59 62585 December 6, 1994]

Appendix - Alternative Sterilization Process Papers

1. Alfa M.J., DeGragne P., Olson N., Puchalski T. Comparison of Ion Plasma, Vaporized Hydrogen Peroxide, and 100% Ethylene Oxide Sterilizers to the 12/88 Ethylene Oxide Gas Sterilizer. Infection Control and Hospital Epidemiology, February 1996;17(2): 87-91.

2. Calhoun L.R., Allen J. T., Shaffer H.L., Sullivan G.M., Williams C.B. Electron-Beam Systems for Medical Device Sterilization. Medical Plastics and Biomaterials Magazine, July 1997.

3. Alfa M.J., DeGragne P., Olson N. Bacterial Killing Ability of 10% Ethylene Oxide Plus 90% Hydochlorofluorocarbon Sterilizing Gas. Infection Control and Hospital Epidemiology, February 1996;18(9): 641-645.

4. Feldman L.A., Hui H.K. Compatibility of Medical Devices and Materials with Low-Temperature Hydrogen Peroxide Gas Plasma. Medical Device & Diagnostic Industry Magazine, December 1997.

5. Arscott E., Anderson S., Broad J.J., Parente D. Validating Radiation Sterilization in a Global Marketplace. Medical Device & Diagnostic Industry Magazine, February 1999.

6. Hemmerich K.J., Polymer Materials Selection for Radiation-Sterilized Products. Medical Device & Diagnostic Industry Magazine, February 2000.

7. Nighswonger G., Keeping a Weather Eye on EtO Sterilization. Medical Device & Diagnostic Industry Magazine, February 2001.

8. Matthews M.A., Warner L.S., Kaiser H. Exploring the Feasibility of Using Dense-Phase Carbon Dioxide for Sterilization. Medical Device & Diagnostic Industry Magazine, May 2001.

9. Mosley G.A., Gillis J.R., Whitbourne J.E. Calculating Equivalent Time for Use in Determining the Lethality of EtO Sterilization Processes. Medical Device & Diagnostic Industry Magazine, February 2002.

10. Allison D.G. and Mohammad S. Traditional or Non-traditional Approaches to the Sterilisation of Medical Devices. Medical Device Manufacturing & Technology, June 2002.

11. Allen D. Sterilization Combination Products. Pharmaceutical & Medical Packaging News, October 2004.